REMARKS

The Examiner is thanked for the due consideration given the application

Claims 28, 29 and 31-55 are pending in the application. Support for the amendments to claim 28 can be founding the specification at page 9, line 36 and page 10, line 12. New claim 55 generally sets forth subject matter from claim 28.

No new matter is believed to be added to the application by this amendment.

Objection to Claim 47

Claim 47 has been objected to as containing an informality. The comments in the Office Action have been considered, and claim 47 has been suitably amended.

Rejections Under 35 USC §103(a) Based on JANSEN

Claims 28, 29, 31-33, and 36-48 have been rejected under 35 U.S.C. §103(a) as being unpatentable over JANSEN (US 2004/0071716; filed 2/20/2002) in view of WESTESEN (US 6,207,178; issued 3/27/2001) and MONDAIN-MONVAL (WO 01/33223; Published May 10, 2001) as evidenced by U.S. 6,866,838..

Claims 28, 34 and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over JANSEN in view of WESTESEN and MONDAIN-MONVAL in view of RABUSSIER (US 3,258,326; issued 6/28/1966).

These rejections are respectfully traversed.

The aim of the present invention is to obtain systems for the administration of active principles, which allow a high concentration of active principle and show a high colloidal stability even at high concentration, thereby avoiding all problems linked to particle aggregation.

The administration systems of the present invention are in the form of a composition of a monodisperse lipid phase dispersed in a continuous aqueous phase. The lipid phase is formed from only at least one crystallizable lipid, at least one active principle, and at least one compound stabilizing the dispersed phase, said at least one stabilizing compound comprising two fatty acid chains and one polyethylene glycol chain, optionally a thickener, and optionally a cryoprotective agent. See claim 28. See also new claim 55.

It is respectfully submitted that such a composition is patentable over the cited prior art.

The disadvantages of JANSEN and WESTESEN have been made of record in the application which, for brevity, are not repeated here. In summary, JANSEN discloses compositions which differ from those presently claimed in particular in that they do not comprise a crystallizable lipid. On the other hand, WESTESEN discloses compositions which include a crystallizable lipid, but are not monodispersed.

The Office Action considers that the skilled person would have been motivated to include the crystallizable lipid of

WESTESEN in the emulsion of JANSEN. Moreover, the Office Action asserts that the skilled person would be motivated to prepare monodisperse particles having a narrow particle size distribution from the teaching of MONDAIN-MONVAL.

However, JANSEN and WESTESEN do not teach or suggest an emulsion the lipid phase of which ***consists of*** the components of the lipid phase of the claimed composition.

In particular, if the skilled person would combine the teaching of JANSEN and WESTESEN to obtain a stable emulsion, he would add the adjuvants described in JANSEN ([0012] - [0031]) in order to obtain a stable emulsion (see [0011] and [0037] of JANSEN). These adjuvants are absent from the lipid phase of the instantly claimed composition.

As a consequence, the emulsion obtained by combining the teachings of JANSEN and WESTESEN does not match the claimed composition. Combining further with the teaching of MONDAIN-MONVAL would not lead either to the claimed composition. Also, a Declaration has been filed attesting to the disadvantages of the applied art.

RABUSSIER fails to address the deficiencies of JANSEN, WESTESEN and MONDAIN-MONVAL set forth above, of record in the application, and in the Declaration.

One or ordinary skill and creativity would thus not produced a claimed embodiment of the present invention from a knowledge of the applied art. A *prima facie* case of

unpatentability has thus not been made, especially in light of the Declaration.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Rejections Under 35 USC §103(a) Based on BIBETTE

Claims 28, 29, 31-39, 41, 44-46 have been rejected under 35 U.S.C. §103(a) as being unpatentable over BIBETTE (WO 01/021297; Published Mar. 29, 2001) in view of WO 99/07463; Published Feb. 18, 1999 (hereinafter WO'463) and NAKAMURA (WO 02/074260; Published Sep. 26, 2002), as evidenced by US 7,214,717, US 6,627,603, and US 2004/0137019 (US'019).

Claims 29, 40, 42, 43, 47, and 48 have been rejected under 35 U.S.C. §103(a) as being unpatentable over BIBETTE in view of '463 and NAKAMURA, as applied to claims 28, 29, 31-39, 41, 44-46 above, and further in view of LIN (US 5,948,855) and KRAFFT (US 5,980,936; Issued Nov. 9, 1999).

These rejections are respectfully traversed.

BIBETTE discloses a double emulsion W/O/W, the lipid phase of which comprises polyglycerol polyricinoleate as emulsifier, The droplets of the internal aqueous phase are monodisperse, but the internal emulsion (i.e., the droplets cornprising both the lipid phase and the internal aqueous phase) is polydisperse (see col. 2, 1. 36-37 of corresponding US 7,214,717).

WO'463 described a multiple W/O/W emulsion, the lipid phase of which may comprise a fat soluble surfactant, such as a polyglycerol polyricinoleate or a polyalkylene dipolyhydrostearate. No general teaching is provided regarding the mono-or poly-dispersity of the emulsion. In examples 1 and 2, the droplets of the internal aqueous phase of the emulsion are described has being monodisperse.

US'019 describes a W/O/W emulsion, the lipid phase of which may comprise liquid or solid oils. The internal emulsion comprises an emulsifier, such as polyethylene glycol dipolyhydroxystearate.

The Office Action is of the opinion that the fat soluble emulsifiers of BIBETTE and WO'463 match the definition of the stabilizing agent as claimed. Moreover, the Office Action considers that BIBETTE and WO'463 disclose double emulsions, the internal emulsions of which are monodisperse. The Office Action asserts that it would be obvious for the skilled person to add the crystallizable lipid of NAKAMURA in the emulsion of BIBETTE and WO'463.

However, first of all, poly***glycerol*** polyricinoleate is not a compound formed from two fatty acid chains and one ***polyethylene glycol*** chain and does therefore not match the definition of the stabilizing agent as claimed, Moreover, the disclosure of a poly***alkylene*** dipolyhydrostearate in WO'463 does

not lead to the disclosure of the stabilizing agent as claimed comprising a polyethylene glycol chain.

Last but not least, the claimed composition comprises a dispersed lipid phase, which is monodisperse, whereas BIBETTE and WO'463 describe double emulsions, the internal agueous phases of which are monodisperse.

None of these three documents disclose an emulsion the lipid phase of which is monodisperse. The skilled person could therefore note have obtained the claimed composition by combining their teachings. A *prima facie* case of unpatentability has thus not been made.

Conclusion

Charge the fee of $52 for the one claim of any type added herewith, to our credit card.

The issuance of a Notice of Allowability is respectfully solicited.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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